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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,530	01/12/2004	Torsten Kuehn	1/1206-1-D1	1325
28501	7590	03/11/2005	EXAMINER ROGERS, DAVID A	
MICHAEL P. MORRIS BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877-0368			ART UNIT 2856	
DATE MAILED: 03/11/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/755,530

Applicant(s)

KUEHN, TORSTEN

Examiner

David A. Rogers

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 February 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 5-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 January 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 8-11 and 14-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an apparatus to detect leaks, does not reasonably provide enablement for and integrity testing apparatus or method using pre-specified pressures. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

In the present application the applicant clearly and unambiguously states that the amount of moisture on the test body is a function of surface area. It is also stated clearly and unambiguously that the amount of moisture released by the test body is a function of time and surface area of the test body (see page 4, line 9). There is no disclosure with regard to determining the pre-determined pressure as a function of the temperature of the integrity system. There is no disclosure with regard to pre-determining the amount of moisture on the test body as a function of storage time, storage temperature, storage humidity levels. Furthermore, the amount of moisture released by the test

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body will be highly influenced by the temperature of the integrity testing process. In fact, in order to establish a pre-determined pressure rise as being indicative of a leaky system the temperature must be held constant. Also, if the temperature is very low then only a small amount of moisture will be released and, coupled with any leaks in the system, may not be sufficient to reach the pre-determined pressure threshold and will give a false indication of a non-leak system. If the temperature is very high then the amount of moisture released will be substantial, and the pressure threshold may be reached/exceeded even if there are no leaks in the system, thus giving a false indication of a leaky system.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 5, 6, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over United States Patent 6,082,184 to Lehmann in view of Japanese Laid-Open Patent Application Publication JP 09323774A to Yoshiga.

Lehmann discloses a test cavity (reference item 1) into which is placed a closed container (reference item 9). Lehmann teaches that it is known to test small, closed containers such as blister packs, vials, medical application

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containers, and food/beverage containers. The closed container comprises a predetermined amount of liquid, as seen in figure 2. A vacuum pump (reference item 5) is connected to the test cavity in order to create a vacuum within the cavity. The internal cavity pressure is monitored using a pressure sensor (reference item 7). In use the container with the liquid in placed in the cavity, the cavity is sealed, and the pump is used to create a vacuum within the cavity. Should the closed container have a leak then the contained liquid will evaporate into the cavity thus increasing the pressure within the cavity which will be indicated by the pressure sensor.

Lehmann does not expressly teach the testing of a closed container comprising polyamide. Yoshiga teaches that it is known to create small, closed polyamide-containing containers for holding liquids, i.e. aerosol containers. Performing a leak test on a closed container such as those taught by Yoshiga would help ensure that those specific containers were produced in an airtight manner, i.e. did not have manufacturing defects prior to shipping and/or use.

*Note: As admitted by the applicant it is an inherent property of polyamide to absorb moisture (see page 4, lines 1-4). The aerosol container of Yoshiga, being primarily manufactured from polyamide, would inherently absorb moisture from its surrounding environment to a predetermined amount and could be reused if desired. This absorbed moisture would then inherently be released into the test chamber's cavity when a vacuum is drawn. See the reference to "Vapor Pressure" by Wikipedia.org which is available on the Internet at <[http://en.wikipedia.org/wiki/Vapor\\_pressure](http://en.wikipedia.org/wiki/Vapor_pressure)>. This moisture release, even with or without any moisture from a leak, will cause the pressure in the chamber*

*of Lehmann to rise. As further admitted by the applicant the amount of moisture released depends on the amount of time the device is exposed to the vacuum and the the amount of absorbed moisture. As noted by Wikipedia.org the temperature will also influence the amount of moisture released by the device.*

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Lehmann with the teachings of Yoshiga in order to perform leak testing of a closed container comprising polyamide.

5. Claims 5, 7, 12, and 13 are is rejected under 35 U.S.C. 103(a) as being unpatentable over United States Patent 6,082,184 to Lehmann in view of United States Patent 5,152,411 to Pope *et al.*

Lehmann discloses a test cavity (reference item 1) into which is placed a closed container (reference item 9). Lehmann teaches that it is known to test small, closed containers such as blister packs, vials, medical application containers, and food/beverage containers. The closed container comprises a predetermined amount of liquid, as seen in figure 2. A vacuum pump (reference item 5) is connected to the test cavity in order to create a vacuum within the cavity. The internal cavity pressure is monitored using a pressure sensor (reference item 7). In use the container with the liquid in placed in the cavity, the cavity is sealed, and the pump is used to create a vacuum within the cavity. Should the closed container have a leak then the contained liquid will evaporate into the cavity thus increasing the pressure within the cavity which will be indicated by the pressure sensor.

Pope *et al.* teaches that it is known to create small, closed container for holding liquids, i.e. aerosol containers, that comprise polyoxymethylene. Performing a leak test on a closed container such as those taught by Pope *et al.* would help ensure that those specific containers were produced in an airtight manner, i.e. did not have manufacturing defects prior to shipping and/or use. See also the note above.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Lehmann with the teachings of Pope *et al.* in order to perform leak testing of a closed container comprising polyoxymethylene.

### **Conclusion**

6. It is known to operate vacuum chambers with and without standard test bodies so that the integrity of the test chamber can be ascertained. For example, periodically drawing a vacuum in the empty test chamber of Lehmann will indicate if the chamber is defective due if there is a measurable increase in pressure. Lehmann also discloses a method to calibrate using moisture (see figure 20). See also Roberts (United States Patent 3,186,214) for calibrating with a test standard.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Rogers whose telephone number is (571) 272-2205. The examiner can normally be reached on Monday - Friday (0730 - 1600).


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hezron E. Williams can be reached on (571) 272-2208. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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07 March 2005

  
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